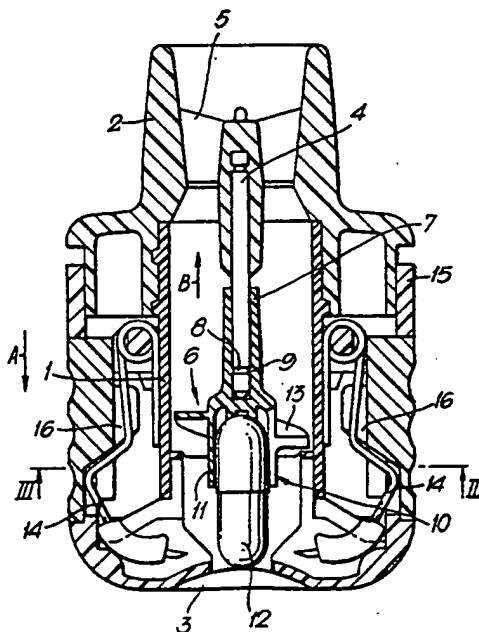




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<b>(21) International Application Number:</b> PCT/GB93/02013 <b>(22) International Filing Date:</b> 23 September 1993 (23.09.93)  <b>(30) Priority data:</b> 9220077.3 23 September 1992 (23.09.92) GB 9220083.1 23 September 1992 (23.09.92) GB  <b>(71) Applicant (for all designated States except US):</b> FISONS PLC [GB/GB]; Fison House, Princes Street, Ipswich, Suffolk IP1 1QH (GB).  <b>(72) Inventors; and</b> <b>(75) Inventors/Applicants (for US only):</b> SHEPHERD, Michael, Trevor [GB/GB]; 59 Chaveney Road, Quorn, Loughborough, Leicestershire LE12 8AB (GB). CLARKE, Alastair, Robert [GB/GB]; 22 Westoby Close, Shepshed, Leicestershire LE12 9SS (GB). RENFREW, Bruce, James [GB/GB]; 1c The Old School House, Park Road, Anstey, Leicester LE7 7AX (GB).		<b>(74) Agent:</b> WRIGHT, Robert, Gordon, McRae; Fisons plc, 12 Derby Road, Loughborough, Leicestershire LE11 0BB (GB).  <b>(81) Designated States:</b> AT, AU, BB, BG, BR, BY, CA, CH, CZ, DE, DE (Utility model), DK, ES, FI, GB, HU, JP, KP, KR, KZ, LK, LU, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, UA, US, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i>

**(54) Title:** INHALATION DEVICE**(57) Abstract**

A medicament inhalation device including a housing (1) defining a throughgoing pathway provided at one end with an air inlet (3), and at the other end with a mouthpiece (2); a drive member (6) rotatably mounted in the housing (1) on a shaft (4) which is coaxial with the longitudinal axis of the housing (1), the drive member (6) having, on a portion adjacent to the air inlet (3), mounting means (10) adapted to engage a medicament capsule (12), and the drive member (6) being so mounted on the shaft (4) that the passage of a stream of air through the pathway causes rotational and vibrational movement of the drive member (6); characterised in that the air inlet (3) is adapted to act as a capsule port through which a capsule (12) can be inserted into the mounting means (10).

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## INHALATION DEVICE

This invention relates to inhalation devices and in particular to devices for the inhalation of powdered medicament contained in capsules.

The administration of inhalation medicaments in dry powder form is well known. Powdered medicament is often supplied in capsules which are loaded into a dispensing device wherein the medicament is released from the capsule then inhaled by the patient.

GB 1122284 (Fisons plc) discloses one such device for the inhalation of powdered medicament from a capsule, a preferred embodiment of this device is sold under the name SPINHALER™. This device has the disadvantage that it must be dismantled for insertion of a capsule prior to inhalation and again to remove the empty capsule after inhalation. Dismantling the device can prove very difficult especially for those with impaired hand movement such as the elderly.

We have now devised an improved inhalation device which overcomes or substantially mitigates the disadvantages of the device described above.

According to the present invention, there is provided a medicament inhalation device including a housing defining a through-going pathway provided at one end with an air inlet, and at the other end with a mouthpiece; a drive member rotatably mounted in the housing on a shaft which is coaxial with the longitudinal axis of the housing, the drive member having, on a portion adjacent to the air inlet, mounting means adapted to engage a medicament capsule, and the drive member being so mounted on the shaft that the passage of a stream of air through the pathway causes rotational and vibrational movement of the drive member; characterised in that the air inlet is adapted to act as a capsule port through which a capsule can be inserted into the mounting means.

In addition, the device according to the invention preferably includes release means to permit removal of a capsule from the mounting means through the air inlet.

Drive members suitable for use in the device according to the invention include propellers having two or more rotor vanes or blades symmetrically disposed about a central axis or hub, such that impingement of an air stream on the rotor vanes or blades causes rotation of the propeller about the axis or hub.

The drive member preferably includes a sleeve-like bearing for mounting over the shaft of the device. The drive member may be freely mounted on the shaft, however, we prefer the drive member to be retained on the shaft by retaining means. The retaining means may comprise a circumferential ridge formed on the interior wall of the sleeve-like bearing which is received by a circumferential recess formed on the shaft or *vice versa*. The retaining means prevents the drive member falling off the shaft if the device needs to be dismantled, e.g. for cleaning.

The vibrational component of the movement of the drive member is essential for release of medicament from the capsule and to obtain constant and reproducible results from the inhalation device. Vibrational movement of the drive member may be effected by controlling the dimensions of said member as described in GB 1122284 and GB 1301856 (Fisons plc) the disclosures of which are incorporated herein by reference.

The device according to the invention preferably includes piercing means for piercing a capsule held in the mounting means. Suitable piercing mechanisms will be apparent to those skilled in the art and include e.g. pins or blades. The piercing means preferably takes the form of one or more, e.g. two, spring biased pins. Piercing of the capsule may be effected by a cam surface moving over the spring biased pins, the reciprocal movement of the cam surface allowing the pins to withdraw from the capsule under their spring bias. When piercing is effected by means of cam surfaces these are preferably provided on the inside of a sleeve slidably mounted on the housing of the device.

Alternatively the device may be used for dispensing medicament contained in pre-pierced capsules, i.e. capsules the walls of which are provided with one or more apertures during manufacture; in this case it is not necessary for the device to include piercing means.

The air inlet of the device must be large enough to enable it to function as a capsule port for the insertion of a medicament capsule into the mounting means. The air inlet preferably comprises a circular aperture having a diameter slightly larger than the diameter of a capsule to be inserted into the mounting means. The device may be provided with additional air inlets, for example, positioned radially around the capsule port air inlet.

The housing of the device may act to guide a capsule inserted through the air inlet into the mounting means, this may be achieved by providing a constriction in the housing between the air inlet and the mounting means. This constriction may also act to restrict the air stream which flows through the pathway upon inhalation by a patient at the mouthpiece, thus increasing the velocity of air past the capsule and aiding in the release of medicament therefrom.

The mounting means preferably includes resilient jaws adapted engage a medicament capsule. When the drive member includes rotor vanes these are preferably integrally moulded with the resilient jaws of the mounting means.

10 The device according to the invention preferably includes release means and mounting means including resilient jaws, wherein movement of the release means from a first position to a second position disengages the capsule from the mounting means. Movement of the release means from a first position to a second position may either move the jaws from an engaged to a disengaged position, or transport the capsule from an engaged to a disengaged position.

When the drive member includes rotor vanes integrally moulded with the resilient jaws then movement of the release means from a first (rest) position to a second (release) position preferably urges the rotor vanes away from the air inlet thereby causing jaws to move from an engaged to a disengaged position.

20 When the release means transports the capsule from an engaged to a disengaged position, the release means preferably includes an ejection arm which is adapted to urge the capsule out of the mounting means and through the air inlet. In a first (rest) position the ejection arm will be retracted from the mounting means and upon movement to a second (release) position will slide up inside the mounting means thereby ejecting the capsule. Movement of the ejection arm may be effected by an expulsion collar slidably mounted on the drive member.

When the device according to the invention includes release means movement of the release means from a first to a second position is preferably effected by a sleeve slidably mounted on the housing. The sleeve preferably performs the dual function of moving the release means and actuating piercing means. Therefore, in a preferred embodiment of the device, movement of the sleeve from a rest position in a direction parallel to the longitudinal axis of housing actuates piercing means for piercing a capsule held in the mounting means; and movement of

30

the sleeve from the rest position in the opposite direction moves the release means from a first position to a second position.

When the device comprises release means this is preferably biased into a first position, i.e. a rest position in which a capsule can be inserted into, and engaged by, the mounting means.

The device may, if desired, be fitted with a non-return valve so that air may only be inhaled and not blown through the device by the patient.

The device may be constructed of any suitable material, preferably of a synthetic thermoplastic resin, e.g. high density polyethylene, acrylonitrile butadiene styrene (ABS), or DELRIN™; in which case it can be made by an injection moulding technique.

Although the device according to the invention has thus far been described for use in oral inhalation of medicaments, it is also suitable for the administration of nasal medicaments by inhalation. The necessary adaptation for this mode of administration will be readily apparent to those skilled in the art.

The capsules for use with the device according to the invention are preferably cylindrical, they may be made from any material which can be pierced, e.g. gelatin.

The device may be used for dispensing any powdered medicament which is conventionally administered by inhalation to the lung or nose. Such medicaments include drugs for use in the prophylactic or remedial treatment of reversible obstructive airways disease. Specific medicaments which may be mentioned include, for example, sodium cromoglycate and nedocromil sodium; inhaled steroids such as beclomethasone dipropionate, tiopredane, and fluticasone; anticholinergic agents such as ipratropium bromide; bronchodilators, e.g. salmeterol, salbutamol, reproterol, terbutaline, albuterol and fenoterol; and salts thereof. If desired a mixture of medicaments, for example a mixture of sodium cromoglycate and a bronchodilator, such as reproterol or a salt thereof, may be used.

Devices according to the invention have advantages over known inhalation devices in that the procedures for insertion of the medicament capsule into the device, and for removal of the empty capsule from the device after inhalation, are considerably simplified. Furthermore, since the device does not need to be dismantled for insertion/removal of the capsule, the patient is less likely to

inadvertently injure themselves on the piercing means; and the propeller-like member, if freely mounted on the shaft, cannot fall off the shaft during the insertion/removal procedure.

The invention will now be described, by way of example only, with reference  
5 to the accompanying drawings, in which:

Figure 1 is a perspective view of a device according to the invention;

Figure 2 is a longitudinal section of the device of Figure 1 in the rest  
position;

Figure 3 is a section along the line III-III of Figure 2;

10 Figure 4 is a longitudinal section of the device of Figure 1 in the release  
position;

Figure 5 is a perspective view of an alternative device according to the  
invention;

Figure 6 is a longitudinal section of the device of Figure 5 in the rest  
15 position;

Figure 7 is a section along the line VII-VII of Figure 6; and

Figure 8 is a longitudinal section of the device of Figure 5 in the release  
position;

In the Figures corresponding features of the alternative devices are given the  
20 same reference numeral.

Referring firstly to Figures 1 to 4: a medicament inhalation device comprises  
a generally cylindrical housing (1) describing a through-going pathway. The housing  
(1) is provided at one end with a mouthpiece portion (2), optionally having a  
removable mouthpiece cover (not shown), and provided at the other end with an air  
25 inlet (3).

A shaft (4) is rigidly mounted coaxially with the housing (1), the end of shaft  
(4) adjacent to the mouthpiece (2) end of housing (1) being supported by cross  
members (5). Propeller (6) having a sleeve-like bearing (7) is mounted on shaft (4).  
Shaft (4) is provided with a circumferential recess (8) which receives a  
30 circumferential ridge (9) formed on the interior wall of bearing (7) such that  
dissociation of the shaft (4) and the propeller (6) is prevented. Propeller (6) is  
provided with a capsule mounting cup (10) comprising four resilient segments (11),  
shown best in Figure 3, which is adapted to engage a capsule (12) containing

powdered medicament to be inhaled. Propeller (6) is also provided with four rotor vanes (13) integrally moulded with segments (11), which cause the propeller (6) to rotate on shaft (4) when air is drawn through the pathway, as during inhalation.

Two stainless steel piercing needles (14), spring biased into the rest position shown in Figures 2, are provided on housing (1). One end of each needle (14) being secured to the housing (1), the other end being curved inwards such that they point towards a capsule (12) engaged by segments (11) of cup (10). A sleeve (15) is slidably mounted on housing (1). Cam surfaces (16) located on the inside of sleeve (15) are adapted to engage piercing needles (14) thus pushing them into a capsule (12) engaged by segments (11) of cup (10) when the sleeve (15) is slid in the direction of arrow A in Figure 2. (The cam surfaces may be integrally moulded with the sleeve, however, for ease of manufacture they may be moulded separately and located in the sleeve during assembly of the device).

At the air inlet (3) end of housing (1) sleeve (15) turns inwards on itself thus defining the walls of the air inlet (3). Sleeve (15) extends further within housing (1) to form a circular release collar (17) which is located between the air inlet (3) and rotor vanes (13). When sleeve (15) is moved in the direction of arrow C in Figure 4 the collar (17) is adapted to apply downwards pressure onto rotor vanes (13) thus urging them away from the air inlet (3), thereby causing the segments (11) of cup (10) to splay outwards. In this position the air inlet end of sleeve (15) urges needles (14) slightly inwards against their bias, this effect may be further enhanced by the provision of cam surfaces within the sleeve.

In use, a capsule (12) containing powdered medicament to be inhaled is inserted through air inlet (3) and engaged by the segments (11) of cup (10). Sleeve (15) is then moved in the direction of arrow A in Figure 2 causing the cam surfaces (16) to engage needles (14) and pierce capsule (12). Reciprocal movement of the sleeve (15) allows needles (14) to withdraw from the pierced capsule (12) under their spring bias.

The patient then inhales through mouthpiece (2), thereby drawing air through the pathway in the direction of arrow B in Figure 2. The flow of air through the pathway causes the propeller (6) to rotate about shaft (4) and also to vibrate. The medicament is thereby dispensed from capsule (12) through the apertures formed by needles (14), entrained in the air flow and inhaled by the patient.



Once the patient has inhaled the medicament, the device is held with the air inlet (3) pointing downwards and sleeve (15) is moved over housing (1) in the direction of arrow C in Figure 4 (this may be achieved by pushing the sleeve and mouthpiece towards each other). Release collar (17) presses onto rotor vanes (13), the pressure on rotor vanes (13) causing segments (11) to splay outwards from the base of cup (10) thus disengaging the empty capsule (12) which falls out of the housing (1) through the air inlet, as shown in Figure 4. The sleeve (15) then returns to its rest position under the bias of needles (14) and the inhalation device is once more ready for use.

10 In an alternative embodiment of the device shown in Figures 5 to 8 the release means includes a cylindrical ejection collar (18) slidably mounted around the housing (1). The collar (18) is provided with projecting lugs (19) which cooperate with corresponding lugs (20) provided on the inside of sleeve (15). Ejection collar (18) is also provided with two transverse arms (21) which project into housing (1).  
15 Arms (21) abut against the base of a secondary ejection collar (22) slidably mounted around sleeve-like bearing (7). The secondary ejection collar (22) has two arms (23) running parallel to bearing (7) which extend through the base of mounting cup (10). Ejection collar (18) is biased into the rest position shown in Figure 6 by spring (24).

In use, a capsule (12) containing medicament to be inhaled is inserted  
20 through air inlet (3) and engaged by the segments (11) of cup (10). Sleeve (15) is then moved in the direction of arrow D in Figure 6 causing the cam surfaces (16) to engage needles (14) and pierce capsule (12). Once the medicament has been inhaled by the patient, sleeve (15) is moved in the direction of arrow E in Figure 8, lugs (19, 20) slide the ejection collar (18) over housing (1) against the bias of spring  
25 (24). The arms (21) of the ejection collar (18) push the secondary ejection collar (22) up the bearing (4) and arms (23) are raised into cup (10) thereby ejecting the empty capsule (12) out of the housing (1) through the air inlet (23). The sleeve (15) then returns to its rest position under the bias of spring (24) and the inhalation device is once more ready for use.

CLAIMS

1. A medicament inhalation device includes a housing (1) defining a through-going pathway provided at one end with an air inlet (3), and at the other end with a mouthpiece (2); a drive member (6) rotatably mounted in the housing (1) on a shaft  
5 (4) which is coaxial with the longitudinal axis of the housing (1), the drive member (6) having, on a portion adjacent to the air inlet (3), mounting means (10) adapted to engage a medicament capsule (12), and the drive member (6) being so mounted on the shaft (4) that the passage of a stream of air through the pathway causes rotational and vibrational movement of the drive member (6); characterised in that  
10 the air inlet (3) is adapted to act as a capsule port through which a capsule (12) can be inserted into the mounting means (10).
2. A medicament inhalation device according to claim 1, wherein the device includes release means (17) to permit removal of a capsule (12) from the mounting means (10) through the air inlet (3).
- 15 3. A medicament inhalation device according to claim 2, wherein the mounting means (10) includes resilient jaws (11) adapted to engage a medicament capsule (12) and movement of the release means (17) from a first position to a second position disengages the capsule (12) from the mounting means (10).
4. A medicament inhalation device according to claim 3, wherein movement of  
20 the release means (17) from a first position to a second position moves the jaws (11) from an engaged to a disengaged position.
5. A medicament inhalation device according to claim 4, wherein the drive member (6) includes rotor vanes (13) integrally moulded with the resilient jaws (11) of the mounting means (10), and movement of the release means (17) from a first to  
25 a second position urges the rotor vanes (13) away from the air inlet (3) thereby causing jaws (11) to move from an engaged to a disengaged position.
6. A medicament inhalation device according to claim 3, wherein movement of the release means (17) upon moving from a first to a second position transports the capsule (12) from an engaged to a disengaged position.
- 30 7. A medicament inhalation device according to claim 6, wherein the release means includes an ejection arm (23) adapted to urge the capsule (12) out of the mounting means (10) and through the air inlet (3).

8. A medicament inhalation device according to any one of the preceding claims, wherein movement of the release means (17) from a first to a second position is effected by a sleeve (15) slidably mounted on the housing (1).

9. A medicament inhalation device according to claim 6, wherein movement of the sleeve (15) from a rest position in a direction parallel to the longitudinal axis of housing (1) actuates piercing means (14) for piercing a capsule (12) held in the mounting means (10); and movement of the sleeve (15) from the rest position in the opposite direction moves the release means (17) from a first to a second position.

10. A medicament inhalation device according to any one of the preceding claims, in which the release means (17) is biased into the first position.

Fig. 1.

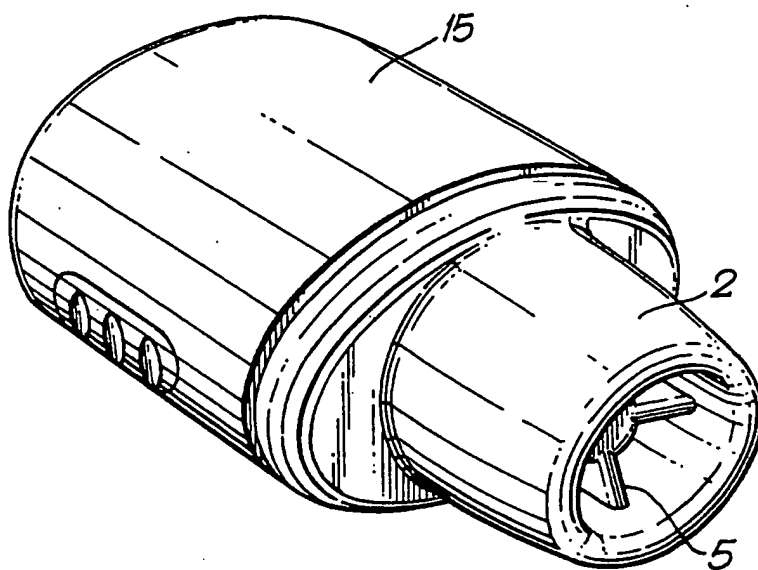
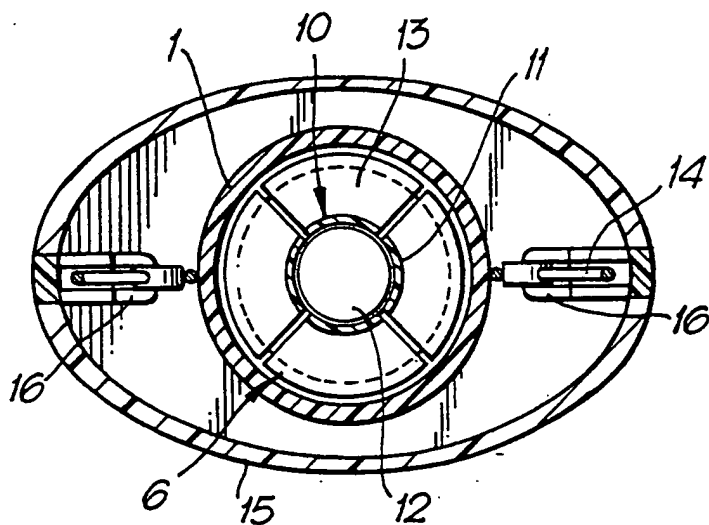


Fig. 3.



*Fig. 2.*

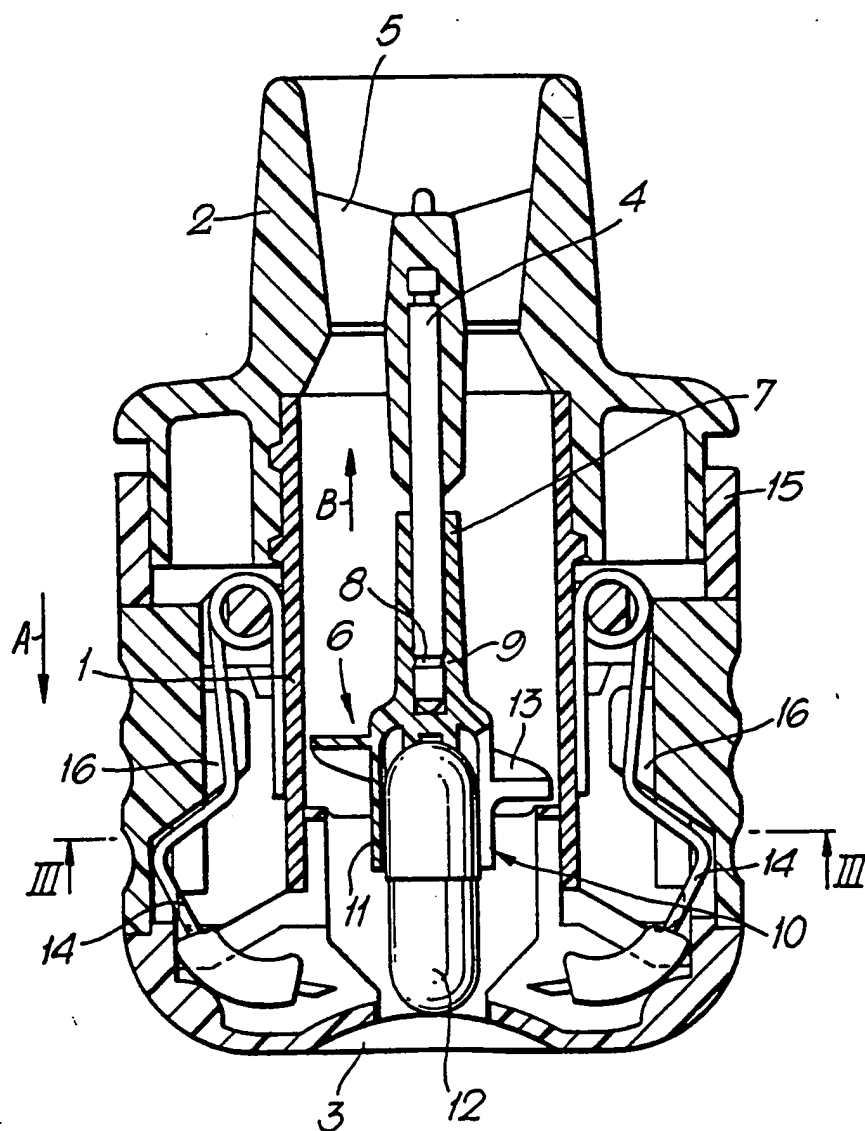


Fig. 4.

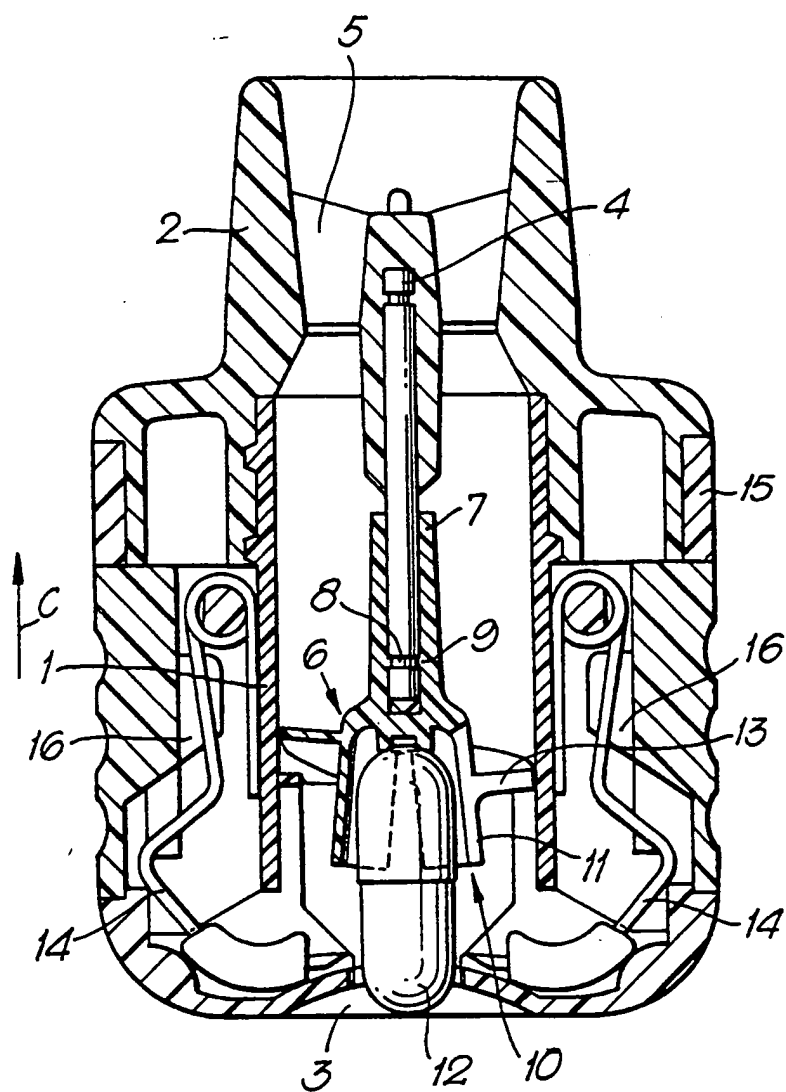


Fig.5.

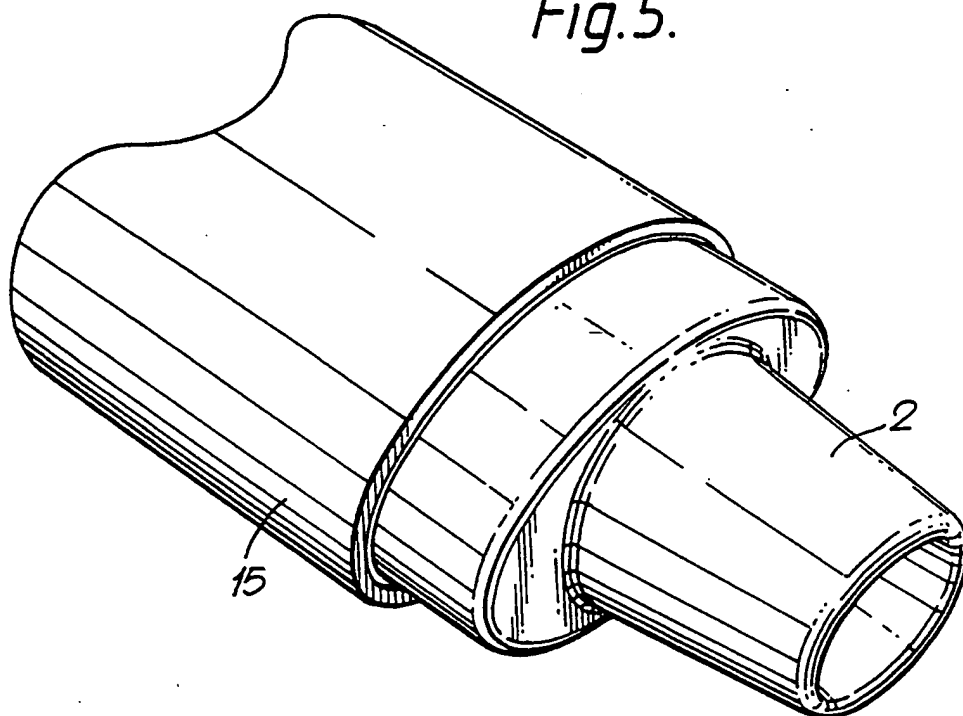


Fig.7.

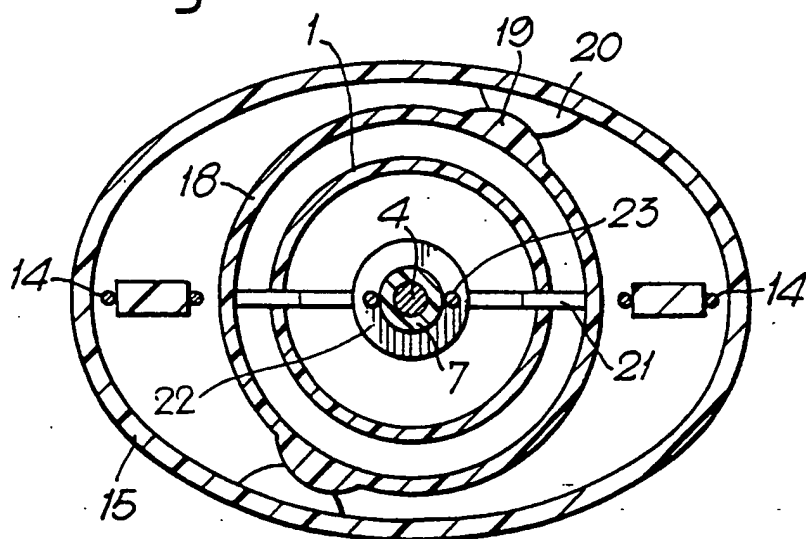
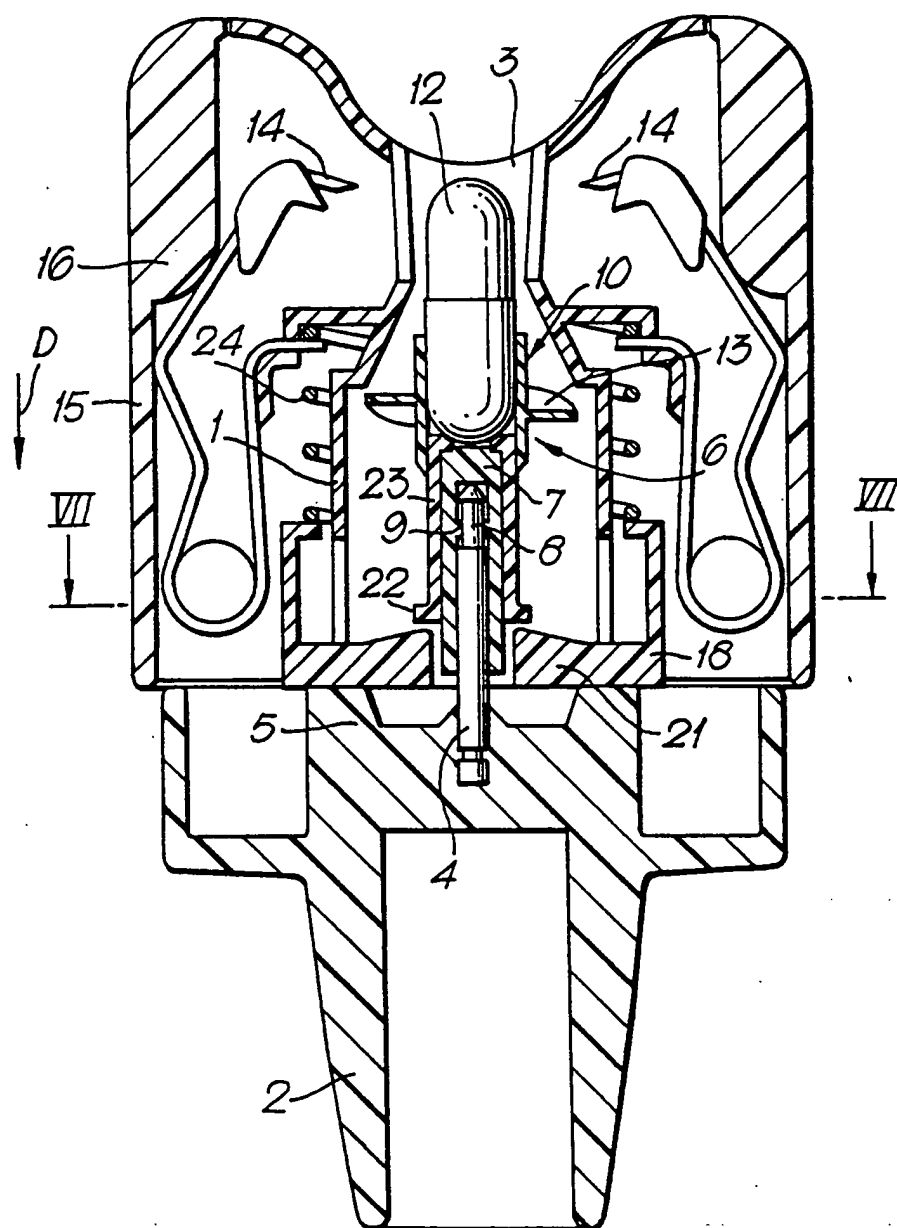
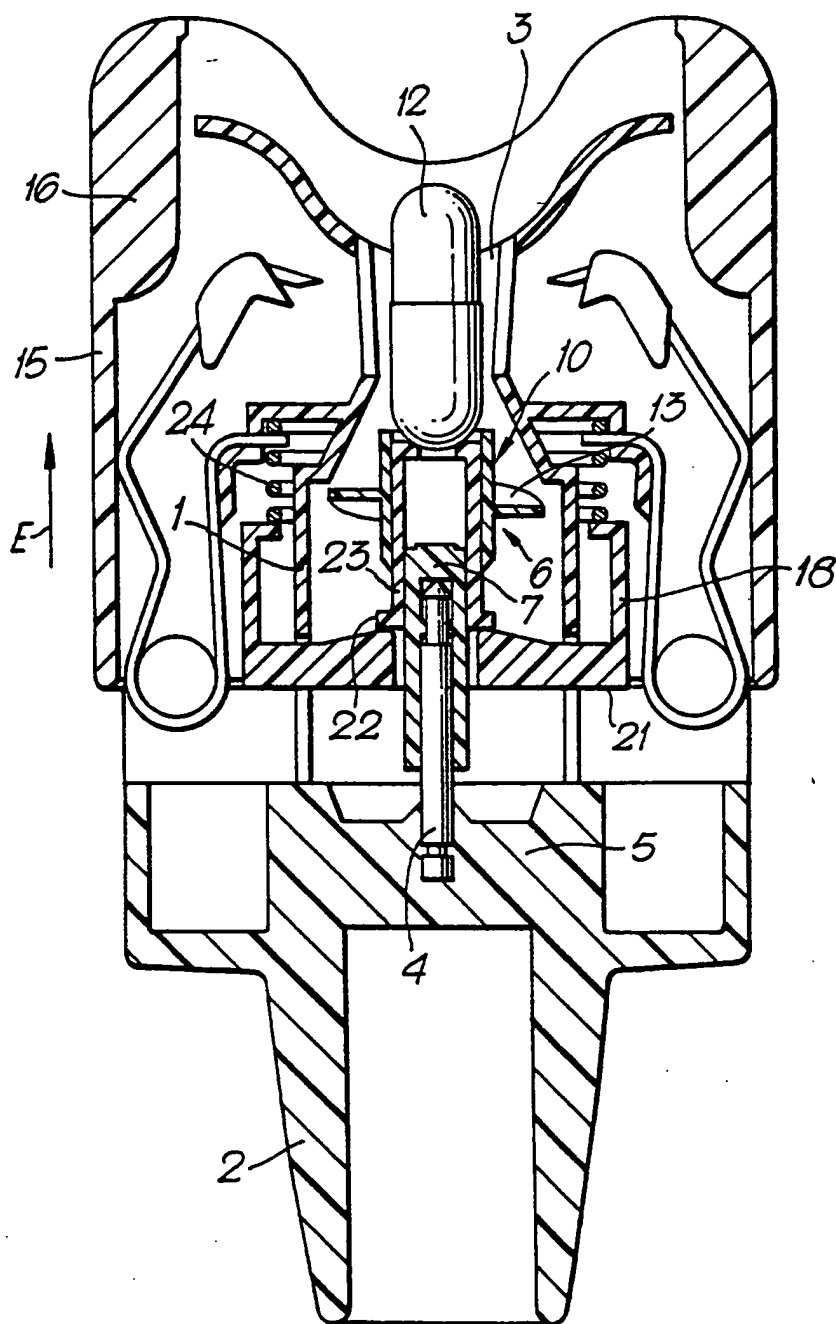


Fig. 6.





*Fig. 8.*



## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/GB 93/02013

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 5 A61M15/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 5 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB,A,1 268 051 (FISONS LTD.) 22 March 1972 see page 3, line 48 - line 61 see page 4, line 23 - line 29; figures ---	1
A	FR,A,2 380 032 (ALLEN & HANBURY LTD.) 8 September 1978 see page 8, paragraph 1; figures ---	2,6-8
A	CH,A,461 035 (FISONS LTD) 15 October 1968 see figures 2,3 -----	9

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☒ Patent family members are listed in annex.

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information on patent family members

International Application No

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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